K101420

SEP 17 2010

GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

Section 6 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 897-4042
Fax: (708) 897-4031

Date Prepared: April 14, 2010

2. Device Name:

Proprietary Name: GC Fuji Temp
Classification Name: Dental Cement
Device Classification: Class II, 872.3275
Product Code: EMA

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
GC America Inc.	Fuji I	K980695	4/13/98
GC America Inc.	Freegenol Temporary Pack	K842994	10/18/84

4. Description of Device:

GC Fuji TEMP is a 2-paste type, glass ionomer provisional luting cement filled in separate syringes, and assembled in one cartridge. With use of Paste Pak Dispenser, GC Fuji TEMP can be dispensed with the appropriate paste ratio.

The applicant device, GC Fuji TEMP is substantially equivalent to the predicate devices in its intended use. Fuji I is intended for final cementation. Freegenol Temporary Pack is intended for temporary cementation. Although the intended periods in oral are different, all devices are used as luting cements.

5. Indications for Use:

- Temporary cementation of crowns and bridges
- Provisional cementation of crowns and bridges on implant abutments

6. Technological characteristics:

GC Fuji TEMP is a 2-paste type, glass ionomer provisional luting cement filled in separate syringes, and assembled in one cartridge. With use of Paste Pak Dispenser, GC Fuji TEMP can be dispensed with the appropriate paste ratio.

GC Fuji TEMP Paste A contains Fluoro-alumino silicate glass (Forming ionic bond with polyacrylic acid, and provides radiopacity and fluoride release), distilled water, viscosity modifying agents, anti-septic agent, and pigments. Paste B contains distilled water, Polyacrylic acid (Forming ionic bond with fluoro-alumino-silicate glass and calcium contained in tooth structure), radiopacity agent, pH adjusting agent, and viscosity modifying agents.

7. Summary of Physical tests:

List of Standards used/results
*ISO 3107: 2004 Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements
*ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements
* Company Specification: AB-15-Q-301-493

Table 8.1.1 Test standards and methods based on ISO standards

	Property	Standards	Test methods	Requirements	Result-qualitative
1	Appearance	ISO 9917-1: 2007 5 Material	Visually inspected before and after paste mixing	·Free from extraneous material ·Homogeneous and smoothly consistent	Within spec set by standard
2	Film thickness	ISO 3107: 2004 Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements, Section 6.4 Determination of film thickness	(150 (+/-) 2) N load is applied for 10 min, 90 sec after start of mix (N=5)	Less than 25µm	Within spec set by standard
3	Setting time	ISO 3107: 2004 Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements, Section 6.2 Determination of setting time	Mixed cement is placed at 37 deg, 180 sec after end of mix. The time when needle fails to penetrate completely 2mm depth of cement is defined, counting from start of mix. (N=2)	4 to 10 min	Within spec set by standard
4	Compressive strength	ISO 3107: 2004 Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements, Section 6.3 Determination of compressive strength	Specimens (6mm high, 4mm in diameter) compressed at 1mm/min (N=5)	Less than 35MPa	Within spec set by standard
5	Acid-soluble lead content	ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1: Powder/liquid, Section 13.2 Acid-soluble lead content	Soaked in lactic acid solution (pH 2.74) for 24 hours. (N=5)	Less than 0.40mm	Within spec set by standard

6	Acid-soluble lead content	ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1: Powder/liquid, Section 13.2 Acid-soluble lead content	Crushed cement after setting is soaked in diluted HCl solution for 16 hours. Eluted lead is detected by atomic absorption or equivalent method. (N=1)	Less than 100mg/kg	Within spec set by standard
7	Radiopacity	ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1: Powder/liquid, Section 14 Radiopacity	Compared to aluminum (N=1)	More than equivalent thickness of aluminum	Within spec set by standard

*ISO 3107:2004 is referred in consideration of clinical use of GC Fuji TEMP, which is relatively used for temporary, although the formulation of GC Fuji TEMP doesn't belong to zinc oxide/eugenol or zinc oxide/non-eugenol cements.

*ISO 9917-1: 2007 is referred in consideration of the formulation of GC Fuji TEMP, which is based on glass polyalkenoate. In that requirement, acid erosion for glass polyalkenoate cements is "Max. 0.17 mm". However, in view of provisional cementation, the criteria for zinc polycarboxylate cements are adopted.

	Property	**Standards and test methods applied**	**Test method**	**Requirements**	
1	Working time	Company Specification: AB-15-Q-301-493	The time when mixed cement becomes rubbery is defined as working time (from start of mix).	2min30sec - 3min30sec (given by the manufacturer)	Within spec set by standard
2	Color	Company Specification: AB-15-Q-301-493	Comparing set cement with standard sample	Equivalent to standard sample	Within spec set by standard
3	Consistency	Company Specification AB-15-Q-301-493	0.5 mL of mixed cement is Loaded with 120g for 10 minutes. Average of long axis and short axis are calculated.	27 – 37 mm (given by the manufacturer)	Within spec set by standard

8. Description of Safety and Substantial Equivalence:

All the components of the applicant device, GC Fuji Temp, have already been used in the predicate devices which are legally marked for the same indications and the same type of tissue contact. This supports the compatibility of GC Fuji Temp and the safety of the applicant device is substantially equivalent to the predicate devices. The new device and predicate devices are similar in function, composition, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Mark Heiss
Director, New Business Development, Academic & Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

SEP 17 2010

Re: K101420
Trade/Device Name: GC Fuji Temp
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 24, 2010
Received: August 25, 2010

Dear Mr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

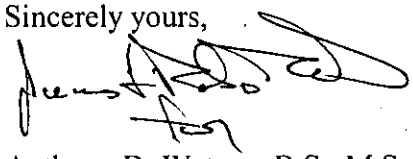
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5

Indications for Use

SEP 17 2010

510(k) Number (if known): _____

Device Name: GC Fuji TEMP

Indications for Use:

- Temporary cementation of crowns and bridges
- Provisional cementation of crowns and bridges on implant abutments

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101420